Fast Track Drug Development Programs: Designation and Review Programs
SOPP 8414
Appendix 1
Fast Track Designation Letter

Our Reference: BB-IND [XXXX]

[SPONSOR'S NAME]
[INSTITUTION'S NAME]
[ADDRESS]

Dear [SPONSOR'S NAME:]

Reference is made to your **Investigational New Drug Application (IND)** for [PRODUCT NAME]. We also refer to your submission of [DATE], received on [DATE], requesting designation as a Fast Track Product pursuant to Section 506 of the Food, Drug, and Cosmetic Act.

We have reviewed your request and concluded that it meets the criteria for the Fast Track designation. Therefore, we are designating as a Fast Track development program the investigation of [PRODUCT NAME] for [CONDITION].

Please note that if the clinical development program you pursue does not continue to meet the criteria for Fast Track designation, the application will not be reviewed under the Fast Track program.

Under the FDA Modernization Act of 1997, designation as a Fast Track product for a new drug or biological product means that FDA will take such actions as are appropriate to expedite the development and review of the application for approval of such product. FDA may also evaluate for filing and commence review of portions of an application for approval of a Fast Track product under certain conditions.

For further information regarding Fast Track Drug Development Programs, please refer to the FDA document "Guidance for Industry on Fast Track Drug Development Programs: Designation, Development, and Application Review". This document is available on the internet at http://www.fda.gov/cber/guidelines.htm or may be requested from the Office of Communications, Training, and Manufacturers Assistance, at (301) 827-1800.

We look forward to working with you to expedite the development and review of this promising proposed use of the product. If you any have questions, please contact [RPM NAME], Division of [DIVISION NAME], at (301) 827-[XXXX].

Sincerely yours,

[DIRECTOR'S NAME]
Director
Division of [XXXXX]
Office of [XXXX]
Research and Review
Center for Biologics
Evaluation and Research

Application Number [BLA/IND/NDA/510(k)/PMA] _____

Letter Type: FAST TRACK DESIGNATION GRANTED (FG)

Cc: Clinical Trial Branch Chief
Clinical Trial Branch/Division Special Assistant
HFM-110/RIMS
HFM-4/QAS
Office Director
HFM-500/B. Goldman
Review Committee
Division Regulatory Project Manager
All Office Division Directors

History

File Name

Concurrence box

Office	Name/Signature	Date